

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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IN RE: FRESENIUS )  
GRANUFLO/NATURALYTE DIALYSATE )  
PRODUCTS LIABILITY LITIGATION )  
This Document Relates to: )  
Mervin Boyd, Individually and as Wrongful )  
Death Beneficiary of Judith Boyd, )  
Case No. 1:13-cv-11717-DPW; )  
Daniel Carter, Individually and on Behalf of the )  
Wrongful Death Beneficiaries of Anniece Carter, )  
Case No. 1:13-cv-12459-DPW; )  
Joyce Marie Clark, Individually and on Behalf of )  
the Wrongful Death Beneficiaries of Edward )  
Lee Jenkins, )  
Case No. 1:13-cv-12460-DPW; )  
Geraldine Dillingham, as Next of Kin and Personal )  
Representative of Estate of Ronnie Dillingham, )  
Case No. 1:15-cv-12796-DPW; )  
Gloria Cothorn Dunaway, Individually and as )  
Wrongful Death Beneficiary of Betty Sue Cothorn, )  
Case No. 1:13-cv-11714-DPW; )  
Carlotta Jerry, Individually and as Next of Kin )  
of Christopher Jerry, )  
Case No. 1:15-cv-14121-DPW; )  
Alex Kazos, as Next of Kin and Personal )  
Representative of Estate of Nick Kazos, )  
Case No. 1:15-cv-12376-DPW; )  
Janice McGhee, Individually and as Wrongful )  
Death Beneficiary of Henry McGhee, )  
Case No. 1:13-cv-13172-DPW; )  
Michael McNulty, Individually and as Wrongful )  
Death Beneficiary of Willie Enette McNulty, )

**REDACTED FILING**

MDL No. 1:13-MD-2428-DPW  
LEAVE TO FILE GRANTED ON  
AUGUST 28, 2017

Case No. 1:13-cv-12403-DPW;	)
	)
Kathleen Palmaccio, as Next of Kin and Personal	)
Representative of Estate of John Palmaccio,	)
Case No. 1:15-cv-12474-DPW;	)
	)
Sharon Randall, as Next of Kin and Personal	)
Representative of Estate of Winfitch Randall,	)
Case No. 1:15-cv-12735-DPW;	)
	)
Amy Riben, Wife, and Max Riben, Husband,	)
And Their Marital Community,	)
Case No. 1:15-cv-11134-DPW;	)
	)
Kimberly Ross, Individually and on Behalf of the	)
Wrongful Death Beneficiaries of Stella Ross,	)
Case No. 1:13-cv-12478-DPW;	)
	)
Sophia Walker, Individually and on Behalf of the	)
Wrongful Death Beneficiaries of Hattie Myles,	)
Case No. 1:13-cv-12487-DPW;	)
	)
Beulah Williams, on Behalf of the Wrongful	)
Death Beneficiaries of Angela Hughes,	)
Case No. 1:13-cv-12486-DPW;	)
	)
Angelos Zachery, et al., Individually and as	)
Executor of the Estate of Nellie Fredrick	)
McClendon,	)
Case No. 1:14-cv-13150-DPW	)
	)

**STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF FMCNA'S  
MOTION FOR SUMMARY JUDGMENT ON THE CLAIMS OF OPT-OUT CASES  
LACKING EVIDENCE OF ELEVATED SERUM BICARBONATE LEVELS**

Pursuant to Federal Rule of Civil Procedure 56 and Local Rule 56.1, Defendants, Fresenius Medical Care Holdings, Inc., Fresenius USA, Inc., Fresenius USA Manufacturing, Inc., and Fresenius USA Marketing, Inc., ("FMCNA") submit this statement of undisputed material facts in support of their motion for summary judgment on the claims of all opt-out plaintiffs who lack evidence of elevated serum bicarbonate levels and whose injuries thus cannot

have been caused by FMCNA, including: Mervin Boyd (Judith Boyd); Daniel Carter (Anniece Carter); Joyce Marie Clark (Edward Lee Jenkins); Geraldine Dillingham (Ronnie Dillingham); Gloria Cothern Dunaway (Betty Sue Cothern); Carlotta Jerry (Christopher Jerry); Alex Kazos (Nick Kazos); Janice McGhee (Henry McGhee); Michael McNulty (Willie Enette McNulty); Kathleen Palmaccio (John Palmaccio); Sharon Randall (Winfitch Randall); Max Riben (Amy Riben); Kimberly Ross (Stella Ross); Sophia Walker (Hattie Myles); Beulah Williams (Angela Hughes); and Angelos Zachery (Nellie Fredrick McClendon).

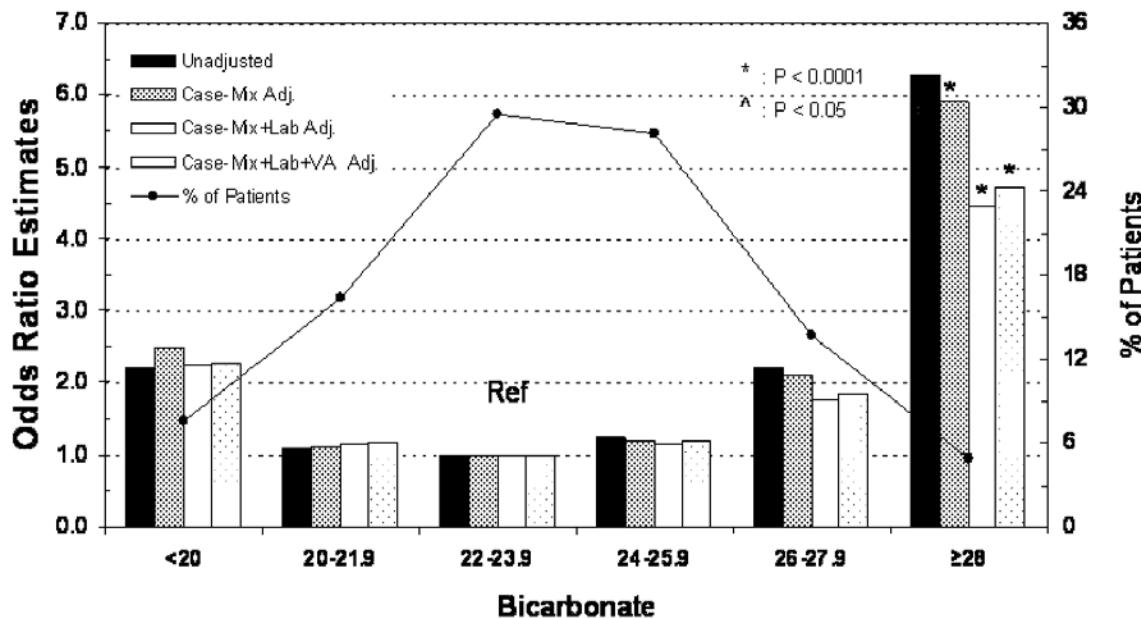
**Facts Applicable to All Plaintiffs**

1. Ray Hakim, MD, former Chief Medical Officer for Fresenius Medical Services, authored a memorandum dated November 4, 2011 (the “Hakim Memo”) that was addressed to medical directors and attending physicians regarding the subject of “Dialysate Bicarbonate, Alkalosis and Patient Safety.” Exhibit 1, FMC-MDL-00027964-69.

2. The Hakim Memo purported to discuss the results of a “case-control study” that “evaluated risk factors in HD patients who suffered from CP arrest in the facility (N=941 patients from 667 facilities) compared to other HD patients (N=80,516) within the same facilities between January 1 and December 31, 2011.” Ex. 1, at p. 3.

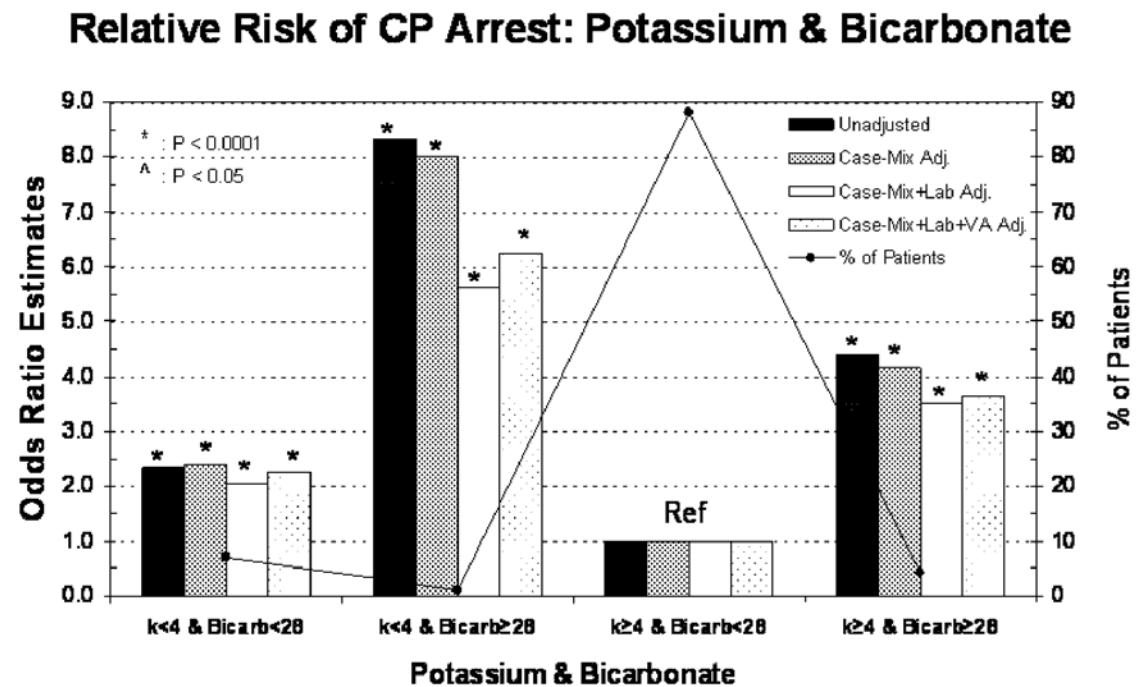
3. At Figure 2, the Hakim Memo included the following graph depicting “Relative Risk of CP Arrest: Bicarbonate”:

## Relative Risk of CP Arrest: Bicarbonate



Ex. 1, p. 3.

4. At Figure 3, the Hakim Memo included the following graph depicting “Relative Risk of CP Arrest: Potassium & Bicarbonate”:



Ex. 1, p. 4.

5. Figures 2 and 3 of the Hakim Memo depicted no statistically significant increased risk of in-center cardiopulmonary arrest for patients with pre-dialysis serum bicarbonate levels in the mid- to low 20s. See Ex. 1, p. 3-4.

6. As set forth in figure 2 in the Hakim Memo, when focusing on bicarbonate alone, patients with a pre-dialysis serum bicarbonate level of 28 or greater were depicted as having the greatest relative risk for cardiopulmonary arrest during dialysis as compared to other groups. No other group was denoted as having a statistically significant increased risk (as indicated by an \* or ^). See Ex. 1, p. 3.

7. As set forth in figure 3 in the Hakim Memo, when pre-dialysis potassium lab values were included in the analysis, patients with a last pre-dialysis serum bicarbonate value under 28 and potassium greater than or equal to 4 had no increased risk, even under Dr. Hakim's analysis (as depicted in the bars labeled "Ref" for reference range). See Ex. 1, p. 4.

8.

9. Plaintiffs retained Derek Fine, MD, as an expert witness on general and specific causation in this litigation. Dr. Fine is an Associate Professor of Medicine at Johns Hopkins University School of Medicine and has a clinical practice that includes treating dialysis patients at a DaVita outpatient dialysis unit in Baltimore, Maryland. Exhibit 3, Report of Derek Fine, M.D. ("Fine Report"), ¶¶ 1, 3.

10. At his deposition, Dr. Fine was asked what he considers a “normal” range for pre-dialysis serum bicarbonate. Ex. 4, June 3, 2015 Deposition of Derek Fine, MD (“Fine Dep.”), 71:19-20. Dr. Fine responded, in part, that there are “varying opinion[s],” but “if I’m talking to my nurse practitioners or my fellows and I’m teaching them, I’d say I’d like to see the bicarb somewhere between, in most cases, 20 and 24.... I would tell them that K/DOQI guidelines say greater than 22 is a reasonable target.” Id. at 71:23 – 72:18.

11. Dr. Fine further testified, in part, that nurse practitioners “usually want you to give them ... a number that you want [them] to worry about” in reviewing pre-dialysis laboratory values and, for him, that number for serum bicarbonate is “something above 26.” Ex. 4, Fine Dep., 73:3-74:1; 75:17-20; 149:1-5. Dr. Fine also testified, in part, “[I]f I’m looking at labs and there’s a 25 and the person was 18 the week before, that may be something I’m going to take into consideration.” Id. at 74:1-3.

12. When asked what number he would select if he could place an “upper limit” for pre-dialysis serum bicarbonate in the KDOQI guidelines, Dr. Fine testified, in part, that “what I’ve told my nurse practitioner is I’ve picked the number of 27.” Ex. 4, Fine Dep., 236:22-237:3, 238:10-14.

13. Dr. Fine further testified, in part:

Q. You said earlier that you teach your nephrology fellows that they should consider the fact that acetate can metabolize into bicarb in the body and factor that in to what is being prescribed. How do you teach them to factor that in?

A. I think what I more do is have them understand that it can be playing a role. Ultimately, I’m – most important is I’m having them focus on the patient’s bicarbonate in their blood and making a judgment based on that. I have one of my fellows who is now terrified to give high bicarb [when using acid concentrates that contain acetate], so she’ll think about it all the time, and I’ll say to her you don’t have to put people on 30 bicarbs, but she understands that if you go down in the bicarb, there’s still that extra 4 and it’s not really that low.

So some of them will take that information and actually adjust behavior, but, in general, you don't need to. Most of our patients aren't alkalic, and so the key that I've really done is made them aware of monitoring that alklosis is bad....

Ex. 4, Fine Dep., 169:11-170:6; see also id. at 70:22-71:11.

14. Dr. Fine uses a standard prescribed bicarbonate setting of 35 at his clinic. Ex. 4, Fine Dep., 223:23 – 224:23. At the time of his deposition, all of his patients at the clinic were on that standard prescription, and he was not aware of any that had been adjusted in the past year.

Id.

15. At his deposition, Dr. Fine testified, in part, that considering the studies and data he reviewed in forming his opinions “the totality of what these studies are showing ... is that high bicarb is bad. High bicarb to me is associated with mortality. High bicarb is associated with sudden cardiac arrest.” Ex. 4, Fine Dep., 337:18-22.

16.

17. Plaintiffs also retained Sushrut Waikar, MD, as an expert witness on general and specific causation in this litigation. Dr. Waikar is an Associate Professor of Medicine at Harvard Medical School and also treats nephrology patients, including some who are on dialysis, at Brigham & Women’s Hospital in Boston. Exhibit 5, Report of Sushrut S. Waikar, MD, MPH (“Waikar Report”), ¶ 1; Exhibit 6, May 26, 2015 Deposition of Sushrut Waikar, MD (“Waikar Dep.”), 11:7-23, 16:12-17:4.

18. At his deposition on May 26, 2015, Dr. Waikar testified, in part, that the “typical serum bicarbonate range is around 20 to 26.” Ex. 6, Waikar Dep., 24:7-8. When asked if there was a range he targeted for his own patients’ pre-dialysis serum bicarbonate levels, Dr. Waikar responded, “22 to 26, around there, would be reasonable, maybe 22 to 24.” Id. at 125:5-13.

19. At his deposition, Dr. Waikar also testified about the circumstances that would lead him to adjust the bicarbonate prescription for a patient, which include “[t]he presence or absence of chronic obstructive pulmonary disease, the presence or absence of severe metabolic alkalosis or acidosis.” Ex. 6, Waikar Dep., 18:12 – 19:7. When asked to explain what he meant when he referred to a patient presenting with metabolic alkalosis, Dr. Waikar gave an example of a patient who “comes into the dialysis unit and the serum bicarbonate concentration is 35.” Id. at 33:9-18. He gave similar examples of a patient with a serum bicarbonate level of 30 or 35 when asked what he meant when he referred to “significant alkalosis.” Id. at 48:5-49:4.

20. Plaintiffs also retained David Goldfarb, MD, as an expert witness on general causation in this litigation. Dr. Goldfarb is a professor at New York University and treats dialysis patients at a VA unit in the New York Harbor Healthcare System. Exhibit 7, June 19, 2015 Deposition of David Goldfarb, MD (“Goldfarb Dep.”), 139:9-13; 76:6-78:1.

21. In discussing bicarbonate levels that would be a potential cause for concern for a patient, Dr. Goldfarb agreed that levels below 22 are “associated with adverse outcomes,” and “so is a bicarbonate of 28 or 30 or 35.” Ex. 7, Goldfarb Dep., 171:15-24. Dr. Goldfarb testified, in part, “Ultimately I’m concerned about the individuals at the extremes.” Id. at 175:16-17.

22. At his deposition, Dr. Goldfarb testified, in part:

Q. For your patients who are on dialysis, and let’s start with now, what’s your practice regarding the bicarbonate prescription?

A. All of the machines are set to deliver a bicarbonate of 35 milliequivalents per liter. The Centrisol concentrate contains 4 milliequivalents of acetate.

Q. You say all the machines are set to 35 bicarbonate. Do any of the treating nephrologists prescribe different levels of bicarbonate?

A. In our chronic dialysis unit, no.

Ex. 7, Goldfarb Dep., 81:7-18.

23. At his deposition, Dr. Goldfarb further testified, in part:

Q. Do any of the treating nephrologists at the New York Harbor clinic change the bicarbonate prescription for their chronic kidney disease patients?

A. I'll ask them that on Monday, but not that I know of. I don't know.

Q. Would you tell them not to if they do?

A. Very likely. My recommendation then would be to say no, I don't think we have a basis for doing that.

Q. Whether they're increasing it or decreasing it you'd – same advice?

A. That's right.

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Q. Do you ever adjust the prescription for treatment based on this [pre- and post-dialysis serum bicarbonate values]?

A. No, I don't.

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Q. So have you looked at one of your patients post-dialysis lab draw and said, oh, that bicarbonate value is too high?

A. Too high, I don't know what that is exactly. But I would say yes, are there numbers that are interesting? Yes. Do I change my prescriptions? No.

Ex. 7, Goldfarb Dep., 92:8-20, 97:6-8, 97:21-98:3.

24. Plaintiffs also retained Steven C. Borkan, MD, as an expert witness on general and specific causation in this litigation. Dr. Borkan is a professor at Boston University and also maintains an active clinical nephrology practice in facilities affiliated with DaVita. Exhibit 8, June 2, 2015 Deposition of Steven Borkan, MD ("June 2, 2015 Borkan Dep."), at 10:22 – 11:9; Exhibit 9, Report of Steven C. Borkan, M.D. ("Borkan Report"), Appendix A, Curriculum Vitae.

25. At his June 2, 2015 deposition, Dr. Borkan testified, in part, that his "target" pre-dialysis serum bicarbonate range for his own patients is between 22 and 24 mEq/L. Ex. 8, June 2, 2015 Borkan Dep., 23:15-21.

26.

27. At the trial held in Florella Dial v. Fresenius Medical Care Holdings, Inc., et al., D. Mass. Case No. 1:14-cv-11101, in February 2017, the plaintiff called Dr. Borkan as a general and case-specific nephrology expert witness. During his trial testimony in Dial, Dr. Borkan testified, in part, that the “normal” pre-dialysis serum bicarbonate level for a dialysis patient is “about 22 to 24 milliequivalents per liter” and confirmed that this also is his personal “target” range for his patients. Exhibit 11, Excerpts from Transcript of Dial Trial (“Dial Trial Tr.”), 2-42, 6-136-138.

28. While on cross-examination during his trial testimony in Dial, Dr. Borkan acknowledged that a laboratory value of 26 mEq/L for pre-dialysis serum bicarbonate could decrease to a lower number within the nephrologist’s target range on its own the next month or two, without any change in prescription. Ex. 11, Dial Trial Tr., 7-78-80.

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32. In his expert report on general causation, Dr. Fine relies on the data discussed in the Hakim Memo to support his opinions. See Ex. 3, Fine Report, pp. 31-34. Dr. Fine also relied on the Hakim Memo at his deposition for his opinion that “alkalosis” is a “trigger” when “someone has an event on dialysis, a cardiopulmonary arrest or cardiac arrest,” and “in patients who are having cardiac events, they’re more likely to have a high bicarbonate.” Ex. 4, Fine Dep., 279:7-19.

33. In his expert report on general causation, Dr. Waikar relies on the data discussed in the Hakim Memo to support his opinions. See Ex. 5, Waikar Report, pp. 6-7 (¶13), 14-15 (¶15), 36 (¶12), 42 (¶14), 45-46 (¶17), 47-48 (¶18), 51 (¶21), 51-52 (¶22), 82 (¶6), 96-98 (¶¶28, 30-31), 164-65 (¶26).

34. Dr. Waikar has never authored a study focused on cardiac arrest and sudden death in dialysis units. Ex. 6, Waikar Dep., 201:15-18.

35. In his expert report on general causation, Dr. Goldfarb relies on the data discussed in the Hakim Memo to support his opinions. See Exhibit 12, Report of David S. Goldfarb, MD (“Goldfarb Report”), at 20-21, 29. At his deposition, Dr. Goldfarb also identified the data discussed in the Hakim Memo as “the data that’s important” to support his opinion that “the increase in serum bicarbonate, the increased bicarbonate, was associated with an increase in sudden death.” Ex. 7, Goldfarb Dep., 202:13 – 206:14; see also id. at 227:16 – 228:8.

36. Dr. Goldfarb himself has never conducted a study on the association of pre-dialysis serum bicarbonate levels and a risk for mortality. Ex. 7, Goldfarb Dep., 282:24 – 283:4.

37. In his expert report on general causation, Dr. Borkan relies on the data discussed in the Hakim Memo to support his opinions. See Ex. 9, Borkan Report, pp. 4, 17-19, 21-23, 26-29, 32. At his June 2, 2015, deposition Dr. Borkan also confirmed that the Hakim Memo is cited throughout his report and is the basis of some of his opinions. Ex. 8, June 2, 2015 Borkan Dep., 144:10-22.

38. Dr. Borkan has never been involved in an observational study looking at modifiable risk factors for sudden cardiac death in dialysis patients. Ex. 8, June 2, 2015 Borkan Dep., 47:8-12. He has never been involved in a study looking at cardiac arrest and sudden death in dialysis units. Id. at 228:2-5.

39. A 2006 article by Dennis Y. Wu and others entitled Association between Serum Bicarbonate and Death in Hemodialysis Patients: Is It Better to Be Acidotic or Alkalotic?, published in the Clinical Journal of American Society of Nephrology, volume 1, pages 70-78, concludes, in part:

The lowest unadjusted mortality was associated with predialysis HCO<sub>3</sub><sup>-</sup> [bicarbonate] in the 17- to 23-mEq/L range, whereas values  $\geq 23$  mEq/L were associated with progressively higher all-cause and cardiovascular death rates. This association, however, reversed after case-mix and MICS multivariate adjustment, so that HCO<sub>3</sub><sup>-</sup> values  $> 22$  mEq/L had lower death risk. Although previous epidemiologic studies indicated an association between high serum HCO<sub>3</sub><sup>-</sup> and increased mortality in MHD [maintenance hemodialysis] patients, this effect seems to be due substantially to the effect of MICS [malnutrition-inflammation complex syndrome] on survival.

Exhibit 13 (at article p. 70).

40. A 2013 article by Francesca Tentori and others entitled Association of Dialysate Bicarbonate Concentration with Mortality in the Dialysis Outcomes and Practice Patterns Study (DOPPS), published in the American Journal of Kidney Disease, concludes, in part:

In the present analysis, serum bicarbonate levels  $> 23$  mEq/L were not associated with increased mortality. ... Our findings are in agreement with results from a

more recent analysis that reported no association between serum bicarbonate level  $>22$  mEq/L and mortality after adjustment for nutritional and inflammatory markers.

Exhibit 14 (at article p. 7-8).

41. A 2015 article by Tadashi Yamamoto and others entitled Predialysis and Postdialysis pH and Bicarbonate and Risk of All Cause and Cardiovascular Mortality in Long-term Hemodialysis Patients, published in the American Journal of Kidney Disease, concludes, in part, “pre- and postdialysis bicarbonate levels were not associated with all-cause and CV [cardiovascular] mortality.” Exhibit 15, p. 1.

42. A 2010 article by F. John Gennari entitled Very Low and High Predialysis Serum Bicarbonate Levels are Risk Factors for Mortality: What are the Appropriate Interventions?, published in Seminars in Dialysis, concludes, in part:

After adjusting for all these factors, the increase in mortality with high levels of [HCO<sub>3</sub>] virtually disappeared, save for values  $> 27$  mmol/l, and mortality increased with low values. ... These data are essentially in agreement with the DOPPS study and again suggest that management of patients with unusually high predialysis serum [HCO<sub>3</sub>] should be directed at management of malnutrition and comorbidity rather than at treating the [HCO<sub>3</sub>] itself.

Exhibit 16 (at article p. 256).

#### **Facts Applicable to Plaintiff Boyd**

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**Facts Applicable to Plaintiff Carter**

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**Facts Applicable to Plaintiff Clark (Decedent Jenkins)**

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**Facts Applicable to Plaintiff Dillingham**

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**Facts Applicable to Plaintiff Dunaway (Decedent Cothern)**

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**Facts Applicable to Plaintiff Jerry**

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**Facts Applicable to Plaintiff Kazos**

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**Facts Applicable to Plaintiff McGhee**

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**Facts Applicable to Plaintiff McNulty**

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**Facts Applicable to Plaintiff Palmaccio**

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**Facts Applicable to Plaintiff Randall**

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**Facts Applicable to Plaintiff Riben**

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**Facts Applicable to Plaintiff Ross**

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**Facts Applicable to Plaintiff Walker (Decedent Myles)**

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**Facts Applicable to Plaintiff Williams (Decedent Hughes)**

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**Facts Applicable to Plaintiff Zachery (Decedent McClendon)**

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Dated: August 28, 2017

Respectfully submitted,

/s/ James F. Bennett \_\_\_\_\_

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**CERTIFICATION OF SERVICE**

I hereby certify that a true and correct copy of the foregoing document was served on Plaintiffs' counsel by e-mail on August 28, 2017, to:

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